R156. Commerce, Occupational and Professional Licensing.
R156-17a. Pharmacy Practice Act Rules.
R156-17a-101. Title.

These rules are known as the "Pharmacy Practice Act Rules".

R156-17a-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 17a, as used in Title 58, Chapters 1 and 17a or these rules:

(1) "Dispense", as defined in Subsection 58-17a-102(9), does not include transferring medications for a patient from a legally dispensed prescription for that particular patient into a daily or weekly drug container to facilitate the patient taking the correct medications.

(2) "NAPLEX" means North American Pharmacy Licensing Examination.

(3) "NABP" means the National Association of Boards of Pharmacy.

(4) "Qualified continuing education" as used in these rules, means continuing education that meets the standards set forth in Section R156-17a-313.

(5) "Unprofessional conduct", as defined in Title 58, Chapters 1 and 17a, is further defined, in accordance with Subsection 58-1-203(5), in Section R156-17a-502.

R156-17a-103. Authority - Purpose.

These rules are adopted by the division under the authority of Subsection 58-1-106(1) to enable the division to administer Title 58, Chapter 17a.

R156-17a-104. Organization - Relationship to Rules R156-1.

The organization of this rule and its relationship to Rule R156-1 is as described in Section R156-1-107.

R156-17a-301. Licensure - Pharmacist - Pharmacy Internship Standards.

In accordance with Subsection 58-17a-302(1)(d), the standards for the internship required for licensure as a pharmacist include the following:

(1) The internship shall consist of at least 1500 hours obtained in Utah, in another state or territory of the United States, or in Utah and another state or territory of the United States.

(a) Internship hours completed in Utah shall include at least 360 hours but not more than 900 hours in a college coordinated practical experience program as an integral part of the curriculum which shall include a minimum of 120 hours in each of the following practices:

(i) community pharmacy;

(ii) hospital pharmacy; and

(iii) another pharmacy setting.

(b) Internship hours completed in another state or territory of the United States shall be accepted based on the approval of hours by the state pharmacy board of that jurisdiction.

(2) Evidence of completed internship hours shall be documented to the division by the pharmacy intern at the time application is made for a Utah pharmacist license or at the completion of the Utah internship, if not seeking Utah licensure.

R156-17a-302. Licensure - Pharmacist - Examinations.

In accordance with Subsection 58-17a-302(1)(e), the examinations which must be successfully passed by applicants for licensure as a pharmacist are:

(1) the NAPLEX with a passing score as established by the NABP;

(2) the Multistate Pharmacy Jurisprudence Examination with a minimum passing score as established by the NABP.

R156-17a-303. Licensure - Pharmacist by Endorsement.

In accordance with Subsections 58-1-203(2) and 58-1-301(3), an applicant for licensure as a pharmacist by endorsement shall apply through the "Licensure Transfer Program" administered by NABP.

R156-17a-304. Licensure - Pharmacy Technician - Education Standards.

(1) In accordance with Subsection 58-17a-302(4)(e), the standards for the program of education and training which is a requirement for licensure as a pharmacy technician shall include:

(a) The program shall consist of at least 300 hours of combined didactic and clinical training to include at a minimum the following topics:

(i) legal aspects of pharmacy practice such as laws and rules governing practice;

(ii) hygiene and aseptic technique;

(iii) terminology, abbreviations and symbols;

(iv) pharmaceutical calculations;

(v) identification of drugs by trade and generic names, and therapeutic classifications;

(vi) filling of orders and prescriptions including packaging and labeling;

(vii) ordering, restocking, and maintaining drug inventory; and

(viii) computer applications in the pharmacy.

(b) The program of education and training shall be outlined in a written plan and shall include a final examination covering at a minimum the topics listed in Subsection (1)(a) above.

(2) The written outline of the training program including the examination shall be available to the division and board upon request.

R156-17a-305. Licensure - Pharmacy Technician - Examinations.

(1) In accordance with Subsection 58-17a-302(4)(e)((ii)(B), the examinations which must be passed by all applicants applying for licensure as a pharmacy technician are:

(a) the Utah Pharmacy Technician Law and Rule Examination with a passing score of at least 75; and

(b) the National Pharmacy Technician Certification Examination with a passing score as established by the Pharmacy Technician Certification Board.

R156-17a-306. Licensure - Pharmacy Intern - Education.

(1) In accordance with Subsection 58-17a-302(5)(a)(i), the approved program is one which is accredited by the American Council on Pharmaceutical Education.

(2) In accordance with Subsection 58-17a-302(5)(b), the preliminary educational qualifications are as defined in Subsection 58-17a-302(5)(b).

(3) In accordance with Subsection 58-17a-302(5)(b), a recognized college or school of pharmacy is one which has a pharmacy program accredited by the American Council on Pharmaceutical Education.

R156-17a-307. Licensure - Preceptor Approval.

In accordance with Subsection 58-17a-102(45), the requirements which must be met by a licensed pharmacist to be approved as a preceptor are:

(1) hold a Utah pharmacist license that is active and in good standing;

(2) have been engaged in active practice as a licensed pharmacist for not less than two years immediately preceding the application for approval as a preceptor, except if employed as a professional experience program coordinator in a pharmacy program accredited by the American Council on Pharmaceutical Education; and

(3) have not been under any sanction at any time which sanction is considered by the division or board to have been of such a nature that the best interests of the intern and the public would not be served by approving the licensee as a preceptor.

R156-17a-308. Licensure - Administrative Inspection.

In accordance with Subsections 58-1-203(2), 58-1-301(3), 58-17a-303(4)(d) and Section 58-17a-103, an administrative inspection may be:

(1) an onsite inspection; or

(2) a self-report inspection completed by the pharmacist-in-charge on an audit form supplied by the division.

R156-17a-309. Licensure - Meet with the Board.

In accordance with Subsections 58-1-203(2) and 58-1-301(3), an applicant for licensure under Title 58, Chapter 17a may be required to meet with the State Board of Pharmacy for the purpose of evaluating the applicant's qualifications for licensure.

R156-17a-310. Licensure - Out-of-state Mail Order Pharmacy.

In accordance with Subsections 58-1-203(2), 58-1-301(3), 58-17a-303(2)(e) and 58-17a-303(4)(d), the application for licensure as an out-of-state mail order pharmacy shall supply sufficient information concerning the applicant's standing in its state of domicile to permit the division and the board to determine the applicant's qualification for licensure in Utah. Such information shall include the following:

(1) a certified letter from the licensing authority of the state in which the pharmacy is located attesting to the fact that the pharmacy is licensed in good standing and is in compliance with all laws and regulations of that state;

(2) an affidavit affirming that the applicant will cooperate with all lawful requests and directions of the licensing authority of the state of domicile relating to the shipment, mailing or delivery of dispensed legend drugs into Utah; and

(3) a copy of the most recent state inspection showing the status of compliance with laws and regulations for physical facility, records, and operations.

R156-17a-311. Licensure - Branch Pharmacy.

In accordance with Subsections 58-1-203(2), 58-1-301(3) and Section 58-17a-614, the qualifications for licensure as a branch pharmacy include the following:

(1) The division in collaboration with the board shall designate the location of each branch pharmacy. The following shall be considered in granting such designation:

(a) the distance between or from nearby alternative pharmacies and all other factors affecting access of persons in the area to alternative pharmacy resources;

(b) the availability at the location of qualified persons to staff the pharmacy consistent with Section R156-17a-609 of these rules;

(c) the availability and willingness of a parent pharmacy and supervising pharmacist to assume responsibility for the branch pharmacy;

(d) the availability of satisfactory physical facilities in which the branch pharmacy may operate; and

(e) the totality of conditions and circumstances which surround the request for designation.

(2) A branch pharmacy shall be licensed as a retail pharmacy branch of an existing retail, hospital, or institutional pharmacy licensed by the division.

(3) The application for designation of a branch pharmacy shall be submitted by the licensed pharmacy seeking such designation. In the event more than one licensed pharmacy makes application for designation of a branch pharmacy location at a previously undesignated location, the division in collaboration with the board, shall review all applications for designation of the branch pharmacy and, if the location is approved, shall approve for licensure the applicant determined best able to serve the public interest.

(4) The application shall include the following:

(a) complete identifying information concerning the applying parent pharmacy;

(b) complete identifying information concerning the designated supervising pharmacist employed at the parent pharmacy;

(c) address and description of the facility in which the branch pharmacy is to be located;

(d) a specific formulary to be stocked indicating with respect to each prescription drug the name, the dosage strength and dosage units in which the drug will be prepackaged;

(e) complete identifying information concerning each person located at the branch pharmacy who will dispense prescription drugs in accordance with the approved protocol; and

(f) protocols under which the branch pharmacy will operate and its relationship with the parent pharmacy to include the following:

(i) the conditions under which prescription drugs will be stored, used, and accounted for;

(ii) the method by which the drugs will be transported from parent pharmacy to the branch pharmacy and accounted for by the branch pharmacy;

(iii) a description of how records will be kept with respect to:

(A) formulary;

(B) changes in formulary;

(C) record of drugs sent by the parent pharmacy;

(D) record of drugs received by the branch pharmacy;

(E) record of drugs dispensed;

(F) periodic inventories; and

(G) any other record contributing to an effective audit trail with respect to prescription drugs provided to the branch pharmacy.

R156-17a-312. Licensure - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer.

In accordance with Subsections 58-1-203(2), 58-1-301(3), and 58-17a-303(2)(h) and (i), the requirements for licensure as a pharmaceutical wholesaler/distributor or pharmaceutical manufacturer are defined, clarified, or established as follows:

(1) Each applicant for licensure as a pharmaceutical wholesaler/distributor or pharmaceutical manufacturer shall provide the following information:

(a) the name, full business address and telephone number;

(b) identification of all trade and business names used by the applicant;

(c) addresses, telephone number and the names of contact persons at all locations in the state in which prescription drugs are located, stored, handled, distributed or manufactured;

(d) a full description of the ownership of the applicant including business type/form, names and identifying information concerning owners, partners, stockholders if not a publicly held company, names and identifying information concerning company officers, and directors and management; and

(e) other information necessary to enable the division in collaboration with the board to evaluate the requirements in Subsection (2) below.

(2) In considering whether to grant a license to an applicant as a pharmaceutical wholesaler/distributor or pharmaceutical manufacturer, the division shall consider the public interest by examining:

(a) any convictions of the applicant under any federal, state or local laws relating to the distribution or manufacturing of prescription drugs, drug samples, controlled substances or controlled substance precursors;

(b) any convictions of a criminal offense or a finding of unprofessional conduct which when considered with the activity of distributing or manufacturing prescription drugs indicates there is or may reasonably be a threat to the public health, safety or welfare if the applicant were to be granted a license;

(c) the applicant's past experience in the distribution or manufacture of prescription drugs including controlled substances to determine whether the applicant might reasonably be expected to be able to engage in the competent and safe distribution and manufacture of prescription drugs;

(d) whether the applicant has ever furnished any false or misleading information in connection with the application or the past activities of the applicant in connection with the distribution or manufacture of prescription drugs;

(e) whether the applicant has been the subject of any action against any license to engage in distribution or manufacture of prescription drugs;

(f) compliance with licensing requirements under any previously granted license to engage in distribution or manufacture of prescription drugs;

(g) compliance with requirements under federal, state or local law to make available to any regulatory authority those records concerning distribution or manufacture of prescription drugs; and

(h) any other factors upon which a reasonable and prudent person would rely to determine the suitability of the applicant to safely and competently engage in the practice of distributing or manufacturing prescription drugs.

(3) The responsible officer or management employee who is responsible for the supervision of the applicant consistent with Section R156-17a-612 shall be identified on the application.

R156-17a-313. Continuing Education - Pharmacist.

(1) In accordance with Subsections 58-1-203(7) and 58-1-308(3)(b), there is created a continuing education requirement as a condition for renewal or reinstatement of pharmacist licenses issued under Title 58, Chapter 17a.

(2) Continuing education shall consist of 24 hours of qualified continuing professional education in each preceding renewal period.

(3) The required number of hours of qualified continuing professional education for an individual who first becomes licensed during the two year period shall be decreased in a pro-rata amount equal to any part of that two year period preceding the date on which that individual first became licensed.

(4) Qualified continuing professional education shall consist of:

(a) institutes, seminars, lectures, conferences, workshops, various forms of mediated instruction, and programmed learning courses presented by an institution, individual, organization, association, corporation, or agency that has been approved by the American Council on Pharmaceutical Education (ACPE);

(b) programs accredited by other nationally recognized healthcare accrediting agencies; and

(c) educational meetings sponsored by the Utah Pharmaceutical Association or Utah Society of Health-System Pharmacists.

(5) Credit for qualified continuing professional education shall be recognized in accordance with the following:

(a) a minimum of eight hours shall be obtained through attendance at lectures, seminars or workshops; and

(b) a minimum of six hours shall be in drug therapy or patient management.

(6) A licensee shall be responsible for maintaining competent records of completed qualified continuing professional education for a period of four years after close of the two year period to which the records pertain. It is the responsibility of the licensee to maintain such information with respect to qualified continuing professional education to demonstrate it meets the requirements under this section.

R156-17a-314. Continuing Education - Pharmacy Technician.

(1) In accordance with Subsections 58-1-203(7) and 58-1-308(3)(b), there is created a continuing education requirement as a condition for renewal or reinstatement of pharmacy technician licenses issued under Title 58, Chapter 17a.

(2) Continuing education shall consist of eight hours of qualified continuing professional education in each preceding renewal period.

(3) The required number of hours of qualified continuing professional education for an individual who first becomes licensed during the two year period shall be decreased in a pro-rata amount equal to any part of that two year period preceding the date on which that individual first became licensed.

(4) Qualified continuing professional education shall consist of:

(a) institutes, seminars, lectures, conferences, workshops, various forms of mediated instruction, and programmed learning courses sponsored or approved by an institution, individual, organization, association, corporation, or agency that has been approved by the American Council on Pharmaceutical Education (ACPE);

(b) programs accredited by other nationally recognized healthcare accrediting agencies; and

(c) educational meetings sponsored by the Utah Pharmaceutical Association or the Utah Society of Health-System Pharmacists.

(5) Documentation of current Pharmacy Technician Certification Board certification will count as meeting the requirement for continuing education.

(6) Credit for qualified continuing professional education shall be recognized in accordance with the following:

(a) a minimum of four hours shall be obtained through attendance at lectures, seminars or workshops.

(7) A licensee shall be responsible for maintaining competent records of completed qualified continuing professional education for a period of four years after close of the two year period to which the records pertain. It is the responsibility of the licensee to maintain such information with respect to qualified continuing professional education to demonstrate it meets the requirements under this section.

R156-17a-315. Renewal Cycle - Procedures.

(1) In accordance with Subsection 58-1-308(1), the renewal date for the two-year renewal cycle applicable to licensees under Title 58, Chapter 17a is established by rule in Section R156-1-308.

(2) Renewal procedures shall be in accordance with Section R156-1-308.

R156-17a-502. Unprofessional Conduct.

"Unprofessional conduct" includes:

(1) violating any provision of the American Pharmaceutical Association Code of Ethics, October 1994, which is hereby incorporated by reference;

(2) failing to comply with the Food and Drug Administration Compliance Policy Guideline 460.200, March 16, 1992, which is hereby incorporated by reference;

(3) failing to comply with the continuing education requirements set forth in these rules;

(4) failing to provide the division with a current mailing address within a reasonable period of time following any change of address;

(5) defaulting on a student loan;

(6) failing to abide by all applicable federal and state law regarding the practice of pharmacy; and

(7) failing to comply with administrative inspections.

R156-17a-601. Operating Standards - Pharmacy Technician - Scope of Practice.

In accordance with Subsection 58-17a-102(42), the scope of practice of a pharmacy technician is defined as follows:

(1) The pharmacy technician may perform any task associated with the physical preparation and processing of prescription and medication orders including:

(a) receiving written prescriptions;

(b) taking refill orders;

(c) entering and retrieving information into and from a database, or patient profile;

(d) preparing labels;

(e) retrieving medications from inventory;

(f) counting and pouring into containers;

(g) placing medications into patient storage containers;

(h) affixing labels;

(i) compounding; and

(j) other non-judgmental tasks.

(2) The pharmacy technician shall not receive new oral prescriptions or medication orders nor perform drug utilization reviews.

(3) The licensed pharmacist on duty can at his discretion provide general supervision as defined in Subsection 58-17a-102(17) to no more than three pharmacy

technicians, only one of which can be an unlicensed technician, who are actually on duty at any one time.

R156-17a-602. Operating Standards - Pharmacy Intern - Scope of Practice.

In accordance with Subsections 58-17a-102(41) and 58-17a-102(41), the scope of practice of a pharmacy intern includes the following:

(1) If a pharmacy intern ceases to meet all requirements for intern licensure, he shall surrender his pharmacy intern license to the division within 60 days unless an extension is requested and granted by the Division in collaboration with the Board.

(2) A pharmacy intern may act as a pharmacy intern only under the supervision of an approved preceptor as set forth in Subsection 58-17a-102(45) and Section R156-17a-603..

R156-17a-603. Operating Standards - Approved Preceptor.

In accordance with Subsection 58-17a-601(1), the following shall apply to an approved preceptor:

(1) He may supervise more than one intern, however, a preceptor may supervise only one intern actually on duty in the practice of pharmacy at any one time.

(2) He shall maintain adequate records to demonstrate the number of internship hours completed by the intern and an evaluation of the quality of the intern's performance during the internship.

(3) The preceptor shall complete the preceptor section of a "Utah Pharmacy Intern Experience Affidavit:"at the conclusion of the preceptor/intern relationship regardless of the time or circumstances under which that relationship is concluded and provide that affidavit to the division.

(4) The preceptor shall be responsible for the intern's acts related to the practice of pharmacy while practicing as a pharmacy intern under his or her supervision.

(5) The preceptor shall use "The Internship Experience, A Manual for Pharmacy Preceptors and Interns", August 1980, published by the NABP or an equivalent manual while providing the intern experience for the intern.

R156-17a-604. Operating Standards - Supportive Personnel.

(1) In accordance with Subsection 58-17a-102(50)(a), the duties of supportive personnel are further defined as follows:

(a) Supportive personnel may assist in any tasks not related to drug preparation or processing including:

(i) stock ordering and restocking;

(ii) cashiering;

(iii) billing;

(iv) filing;

(v) housekeeping; and

(vi) delivery.

(b) Supportive personnel shall not enter information into a patient profile nor accept refill information.

(2) In accordance with Subsection 58-17a-102(50)(b), the supervision of supportive personnel is defined as follows:

(a) All supportive personnel shall be under the supervision of a licensed pharmacist.

(b) The licensed pharmacist shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the services being performed.

(3) In accordance with Subsection 58-17a-601(1), a pharmacist, pharmacy intern, or pharmacy technician whose license has been revoked or is suspended shall not be allowed to provide any support services in a pharmacy.

R156-17a-605. Operating Standards - Medication Profile System.

In accordance with Subsections 58-17a-601(1) and 58-17a-604(1), the following operating standards shall apply with respect to medication profile systems:

(1) Patient profiles, once established, shall be maintained by a pharmacist in a pharmacy dispensing to patients on a recurring basis for a minimum of one year from the date of the most recent prescription filled or refilled; except that a hospital pharmacy may delete the patient profile for an inpatient upon discharge if a record of prescriptions is maintained as a part of the hospital record.

(2) Information to be included in the profile shall be determined by a responsible pharmacist at the drug outlet but shall include as a minimum:

(a) full name of patient, address, telephone number, date of birth or age and gender;

(b) patient history where significant, including known allergies and drug reactions, and a comprehensive list of medications and relevant devices;

(c) a list of all prescription drugs obtained by the patient at the pharmacy including;

(i) name of prescription drug;

(ii) strength of prescription drug;

(iii) quantity dispensed;

(iv) date of filling or refilling;

(v) charge for the prescription drug as dispensed to the patient; and

(d) any additional comments relevant to the patient's drug use.

(3) Patient medication profile information shall be recorded by a pharmacist, pharmacy intern, or pharmacy technician.

R156-17a-606. Operating Standards - Patient Counseling.

In accordance with Subsection 58-17a-601(1), standards for patient counseling established in Section 58-17a-612 include the following:

(1) Patient counseling shall include when appropriate the following elements:

(a) the name and description of the prescription drug;

(b) the dosage form, dose, route of administration, and duration of drug therapy;

(c) intended use of the drug and expected action;

(d) special directions and precautions for preparation, administration, and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescription refill information;

(i) action to be taken in the event of a missed dose;

(j) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and

(k) the date after which the prescription should not be taken or used.

(2) Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drugs.

(3) A pharmacist shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation.

(4) The offer to counsel shall be documented and said documentation shall be available to the division and the board.

R156-17a-607. Operating Standards - Prescriptions.

In accordance with Subsection 58-17a-601(1), the following shall apply to prescriptions:

(1) A prescription issued by an authorized licensed practitioner, if communicated by an agent or employee of that practitioner upon that practitioner's specific instruction and authorization, may be accepted by a pharmacist or pharmacy intern.

(2) Prescription files, including refill information, shall be maintained for a minimum of five years by either a manual filing of written prescriptions or by permanent electronic record.

(3) Prescriptions having a remaining authorization for refill may be transferred by the pharmacist at the outlet holding the prescription to a pharmacist at another outlet upon the authorization of the patient to whom the prescription was issued. The transferring pharmacist and receiving pharmacist shall act diligently to ensure that the total number of authorized refills is not exceeded.

(4) Prescriptions for terminal patients in licensed hospices, home health agencies, or nursing homes may be partially filled if the patient has a medical diagnosis documenting a terminal illness.

R156-17a-608. Operating Standards - Pharmacist-in-charge.

All drug outlets, except pharmaceutical manufacturers and pharmaceutical wholesaler/distributors, and all pharmaceutical administration facilities shall have a pharmacist-in-charge.

R156-17a-610. Operating Standards - Drug Outlets.

In accordance with Subsection 58-17a-601(1), standards for the operations of drug outlets include the following:

(1) Any drug outlet licensed under the Pharmacy Practice Act, Title 58, Chapter 17a, shall be well lighted, well ventilated, clean and sanitary.

(2) The dispensing area, if any, shall have a sink with hot and cold culinary water separate and apart from any rest room facilities.

(3) The drug outlet shall be equipped to permit the orderly storage of prescription drugs and devices in a manner to permit clear identification, separation, and easy retrieval of products, and an environment necessary to maintain the integrity of the product inventory.

(4) The drug outlet shall be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility.

(5) The drug outlet shall be stocked with the quality and quantity of product necessary for the facility to meet it's scope of practice in a manner consistent with the public health, safety and welfare.

(6) The drug outlet shall be equipped with a security system to permit detection of entry at all times when the facility is closed.

(7) Drug outlets engaged in extensive compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility.

(8) The drug outlet shall have recent editions of the following reference publications in such quantity and in such places as to make them readily available to facility personnel:

(a) the Utah Pharmacy Practice Act;

(b) the Utah Pharmacy Practice Act Rules;

(c) the Utah Controlled Substance Act;

(d) the Utah Controlled Substance Act Rules;

(e) Code of Federal Regulations (CFR) 21, Food and Drugs, Part 1300 to end or equivalent such as the USPDI;

(f) current FDA Approved Drug Products (orange book);

(g) any other general drug references necessary to permit practice dictated by the usual and ordinary scope of practice to be conducted within that facility; and

(h) "The Intern Experience, A Manual for Pharmacy Preceptors and Interns", August 1980, published by the National Association of Boards of Pharmacy, if pharmacy interns are present.

(9) The drug outlet shall post in view of the public the license of the facility and the license or a copy of the license of each pharmacist, pharmacy intern, and pharmacy

technician who is employed in the facility, but may not post the license of any pharmacist, pharmacy intern, or pharmacy technician not actually employed in the facility.

(10) Drug outlets initially licensed or substantially remodeled on or after September 1, 1992, shall have a counseling area to allow for confidential patient counseling, when appropriate.

(11) If the pharmacy is located within a larger facility such as a grocery or department store, and a licensed Utah pharmacist is not immediately available in the facility, the pharmacy shall not remain open to pharmacy patients and shall be locked in such a way as to bar entry to the public or any non-pharmacy personnel.

(12) All pharmacies located within a larger facility shall be locked and enclosed in such a way as to bar entry to the public or any non-pharmacy personnel when the pharmacy is closed.

(13) Only a licensed Utah pharmacist or his designee shall have access to the pharmacy when the pharmacy is closed.

R156-17a-611. Operating Standards - Nuclear Pharmacy.

In accordance with Subsections 58-17a-303(4)(d) and 58-17a-601(1), the operating standards for nuclear pharmacies include the following:

(1) A nuclear pharmacy shall have the following:

(a) a current Utah Radioactive Materials License; and

(b) adequate space and equipment commensurate with the scope of services required and provided.

(2) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable standards of quality assurance.

(3) Nuclear pharmacies shall maintain a library commensurate with the level of radiopharmaceutical service to be provided.

(4) A licensed Utah pharmacist shall be immediately available on the premises at all times when the facility is open or available to engage in the practice of pharmacy.

(5) In addition to Utah licensure, the pharmacist shall be currently certified by the Board of Pharmaceutical Specialties in Nuclear Pharmacy or have equivalent classroom and laboratory training and experience as required by the Utah Radiation Control Rules.

(6) This rule does not prohibit:

(a) a licensed pharmacy intern or technician form acting under the direct supervision of an approved preceptor who meets the requirements to supervise a nuclear pharmacy; or

(b) a Utah Radioactive Materials licensee from possessing and using radiopharmaceuticals for medical use.

(7) A hospital nuclear medicine department or an office of a physician/surgeon, osteopathic physician/surgeon, veterinarian, podiatric physician, or dentist that has a current Utah Radioactive Materials License does not require licensure as a nuclear pharmacy.

R156-17a-612. Operating Standards - Pharmaceutical Wholesaler/Distributor and Pharmaceutical Manufacturer located in Utah.

In accordance with Subsection 58-17a-601(1), the operating standards for pharmaceutical wholesaler/distributor and pharmaceutical manufacturer licensee includes the following:

(1) A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs.

(2) A separate license shall be obtained for wholesale distribution activity and manufacturing activity.

(3) The licensee need not be under the supervision of a licensed pharmacist, but shall be under the supervision of a responsible officer or management employee.

(4) There has not been established minimum requirements for persons employed by persons engaged in the distribution or manufacture of prescription drugs; however, this does not relieve the person who engages in the distribution of prescription drugs within the state or in interstate commerce into or from the state, or those engaged in the

manufacture of prescription drugs in the state or in interstate commerce into or from the state from ensuring that persons employed by them have appropriate education, experience, or both to engage in the duties to which they are assigned and do so in a manner which does not jeopardize the public health, safety or welfare.

(5) All facilities associated with the distribution or manufacture of prescription drugs shall:

(a) be of suitable size and construction to facilitate cleaning, maintenance and proper operations;

(b) have storage areas designed to provide adequate lighting, ventilation, sanitation, space, equipment and security conditions;

(c) have the ability to control temperature and humidity within tolerances required by all prescription drugs and prescription drug precursors handled or used in the distribution or manufacturing activities of the applicant or licensee;

(d) provide for a quarantine area for storage of prescription drugs and prescription drug precursors that are outdated, damaged, deteriorated, misbranded, adulterated, opened or unsealed containers that have once been appropriately sealed or closed, or in any other way unsuitable for use or entry into distribution or manufacture;

(e) be maintained in a clean and orderly condition, and

(f) be free from infestation by insects, rodents, birds, or vermin of any kind.

(6) In regard to security, all facilities used for wholesale drug distribution or manufacturing of prescription drugs shall:

(a) be secure from unauthorized entry;

(b) limit access from the outside to a minimum in conformance with local building and life/safety codes, and control access of persons to ensure unauthorized entry is not made;

(c) limit entry into areas where prescription drugs or prescription drug precursors are held to authorized persons who have a need to be in those areas;

(d) be well lighted on the outside perimeter;

(e) be equipped with an alarm system to permit detection of entry and notification to appropriate authorities at all times when the facility is not occupied for the purpose of engaging in distribution or manufacture of prescription drugs; and

(f) be equipped with security measures, systems and procedures necessary to provide reasonable security against theft and diversion of prescription drugs or alteration or tampering with computers and records pertaining to prescription drugs or prescription drug precursors.

(7) In regard to storage, all facilities shall provide for storage of prescription drugs and prescription drug precursors in accordance with the following:

(a) all prescription drugs and prescription drug precursors shall be stored at appropriate temperature, humidity and other conditions in accordance with labeling of such prescription drugs or prescription drug precursors or with requirements in the United States Pharmacopeia/National Formulary (USP/NF), 1995 edition, through Supplement 4, dated August 1, 2001, which is hereby incorporated by reference;

(b) if no storage requirements are established for a specific prescription drug or prescription drug precursor, the products shall be held in a condition of controlled temperature and humidity as defined in the USP/NF to ensure that its identity, strength, quality, and purity are not adversely affected; and

(c) there shall be established a system of manual, electromechanical or electronic recording of temperature and humidity in the areas in which prescription drugs or prescription drug precursors are held to permit review of the record and ensure that the products have not been subjected to conditions which are outside of established limits.

(8) In regard to examination of materials, each facility shall provide that:

(a) upon receipt, each outside shipping container containing prescription drugs or prescription drug precursors shall be visually examined for identity and to prevent the acceptance of prescription drugs or prescription drug precursors that are contaminated, reveal damage to the containers or are otherwise unfit for distribution; and

(b) each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(9) In regard to returned, damaged, and outdated prescription drugs, each facility shall provide that:

(a) prescription drugs or prescription drug precursors that are outdated, damaged, deteriorated, misbranded, adulterated, or in any other way unfit for distribution or use in manufacturing shall be quarantined and physically separated from other prescription drugs or prescription drug precursors until they are appropriately destroyed or returned to their supplier;

(b) any prescription drug or prescription drug precursor whose immediate sealed or outer secondary sealed container has been opened or in any other way breached shall be identified as such and shall be quarantined and physically separated from other prescription drugs and prescription drug precursors until they are appropriately destroyed or returned to their supplier; and

(c) if the condition or circumstances surrounding the return of any prescription drug or prescription drug precursor cast any doubt on the product's safety, identity, strength, quality, or purity, then the drug shall be appropriately destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the product meets appropriate and applicable standards related to the product's safety, identity, strength, quality, and purity.

(10) In regard to record keeping, pharmaceutical wholesaler/distributors and pharmaceutical manufacturers shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription drug precursors and shall make inventories of prescription drugs and prescription drug precursors and required records available for inspection by authorized representatives of the federal, state and local law enforcement agencies in accordance with the following:

(a) there shall be a record of the source of the prescription drugs or prescription drug precursors to include the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(b) there shall be a record of the identity and quantity of the prescription drug or prescription drug precursor received, manufactured, distributed or shipped, or otherwise disposed of by specific product and strength;

(c) there shall be a record of the dates of receipt and distribution or other disposal of any product;

(d) there shall be a record of the identity of persons to whom distribution is made to include name and principal address of the receiver, and the address of the location to which the products were shipped;

(e) inventories of prescription drugs and prescription drug precursors shall be made available during regular business hours to authorized representatives of federal, state and local law enforcement authorities;

(f) required records shall be made available for inspection during regular business hours to authorized representatives of federal, state and local law enforcement authorities, and such records shall be maintained for a period of two years following disposition of the products; and

(g) records that are maintained on site or immediately retrievable from computer or other electronic means shall be made readily available for authorized inspection during the retention period; or if records are stored at another location, they shall be made available within two working days after request by an authorized law enforcement authority during the two year period of retention.

(11) In regard to written policies and procedures, pharmaceutical wholesaler/distributors and pharmaceutical manufacturers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, manufacture, distribution or other disposal of prescription drugs or prescription drug precursors, including policies and procedures for identifying,

recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, the policies shall include the following:

(a) a procedure whereby the oldest approved stock of a prescription drug or precursor product is distributed or used first, with a provision for deviation from the requirement if such deviation is temporary and appropriate;

(b) a procedure to be followed for handling recalls and withdrawals of prescription drugs adequate to deal with recalls and withdrawals due to:

(i) any action initiated at the request of the Food and Drug Administration of other federal, state or local law enforcement or other authorized administrative or regulatory agency;

(ii) any voluntary action by the pharmaceutical wholesaler/distributor or pharmaceutical manufacturer to remove defective or potentially defective drugs from the market; or

(iii) any action undertaken to promote public health, safety or welfare by replacing of existing product with an improved product or new package design;

(c) a procedure to ensure that a pharmaceutical wholesaler/distributor or pharmaceutical manufacturer prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency;

(d) a procedure to ensure that any outdated prescription drugs or prescription drug precursors shall be segregated from other drugs or precursors and either returned to the manufacturer, other appropriate party or appropriately destroyed;

(e) a procedure providing for documentation of the disposition of outdated, adulterated or otherwise unsafe prescription drugs or prescription drug precursors and the maintenance of that documentation available for inspection by authorized federal, state, or local authorities for a period of two years after disposition of the product.

(12) In regard to responsible persons, pharmaceutical wholesaler/distributors and pharmaceutical manufacturers shall establish, maintain and make available for inspection by authorized federal, state and local law enforcement authorities, lists of all officers, directors, managers, and other persons in charge of wholesale drug distribution, manufacture, storage, and handling, which lists shall include a description of their duties and a summary of their background and qualifications.

(13) In regard to compliance with law, pharmaceutical wholesalers/distributors and pharmaceutical manufacturers shall:

(a) operate in compliance with applicable federal, state and local laws and regulations;

(b) permit the state licensing authority and authorized federal, state, and local law enforcement officials, upon presentation of proper credentials, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating policies and procedures, at reasonable times and in a reasonable manner, to the extent authorized by law; and

(c) obtain a controlled substance license from the division and register with the Drug Enforcement Administration (DEA) if they engage in distribution or manufacture of controlled substances, and shall comply with all federal, state and local regulations applicable to the distribution or manufacture of controlled substances.

(14) In regard to salvaging and processing, pharmaceutical wholesalers/distributors and pharmaceutical manufacturers shall be subject to and shall abide by applicable federal, state and local laws that relate to the salvaging or reprocessing of prescription drug products.

(15) A person who is engaged in the wholesale distribution or manufacturing of prescription drugs but does not have a facility located within Utah in which prescription drugs are located, stored, distributed or manufactured is exempt from Utah licensure as a pharmaceutical wholesaler/distributor or a pharmaceutical manufacturer, if said person is currently licensed and in good standing in each state of the United States in which that person has a facility engaged in distribution or manufacturing of prescription drugs entered into interstate commerce.

R156-17a-613. Operating Standards - Animal Euthanasia Agency.

In accordance with Subsection 58-17a-601(1), operating standards for an animal euthanasia agency concerning the use of prescription drugs shall include:

(1) A veterinarian licensed in Utah shall supervise the use of prescription drugs used for animal euthanasia.

(2) The veterinarian shall be responsible for:

(a) identifying each euthanasia drug for which authorization is requested;

(b) identifying the location where euthanasia drugs and records will be maintained;

(c) identifying each person to be authorized to purchase, possess, or administer euthanasia drugs;

(d) describing the training program for each person authorized to purchase, possess, or administer euthanasia drugs as well as attesting to be responsible for that training; and

(e) maintaining euthanasia drug records.

R156-17a-614. Operating Standards - Analytical Laboratory.

In accordance with Subsection 58-17a-601(1), operating standards for an analytical laboratory concerning the use of prescription drugs shall include:

(1) the supervising laboratory director is identified; and

(2) the protocols describing how authorized prescription drugs will be purchased, stored, used, and accounted for are available for division inspection.

R156-17a-615. Operating Standards - Pharmaceutical Researcher.

In accordance with Subsection 58-17a-601(1), operating standards for a pharmaceutical researcher concerning the use of prescription drugs shall include:

(1) requesting and receiving authorization for each drug to be bought or used; and

(2) the protocols describing how authorized prescription drugs will be purchased, stored, used, and accounted for are available for division inspection.

R156-17a-616. Operating Standards - Pharmaceutical Dog Trainer.

In accordance with Subsection 58-17a-601(1), operating standards for a pharmaceutical dog trainer concerning the use of prescription drugs shall include:

(1) affiliation with a law enforcement official from a Utah law enforcement agency who is responsible for the purchase, storage, and use of the authorized prescription drugs;

(2) requesting and receiving authorization for each drug to be bought or used; and

(3) the protocols describing how authorized prescription drugs will be purchased, stored, used, and accounted for are available for division inspection.

R156-17a-617. Operating Standards - Issuing Prescription Orders by Electronic Means.

In accordance with Subsection 58-17a-102(46), prescription orders may be issued by electronic means of communication according to the following:

(1) Prescription orders for Schedule II - V controlled substances received by electronic means of communication shall be handled according to the rules of the federal Drug Enforcement Administration.

(2) Prescription orders for noncontrolled substances received by electronic means of communication may be dispensed by a pharmacist or pharmacy intern only if all of the following conditions are satisfied:

(a) All electronically transmitted prescription orders shall include the following:

(i) all information that is required to be contained in a prescription order pursuant to Section 58-17a-602;

(ii) the time and date of the transmission, and if a facsimile transmission, the electronically encoded date, time, and fax number of the sender; and

(iii) the name of the pharmacy intended to receive the transmission.

(b) The prescription order shall be transmitted by an authorized prescriber or his designated agent.

(c) The pharmacist shall exercise professional judgment regarding the accuracy and

authenticity of the transmitted prescription. The pharmacist is responsible for assuring that each electronically transferred prescription order is valid and shall authenticate a prescription order issued by a licensed prescriber which has been transmitted to the dispensing pharmacy before filling it, whenever there is a question.

(d) An electronically transmitted prescription order that meets the requirements above shall be deemed to be the original prescription.

(3) This section does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical facilities.

(4) No agreement between a prescriber and a pharmacy shall require that prescription orders be transmitted by electronic means from the prescriber to only that pharmacy.

(5) Wholesalers, distributors, manufacturers, pharmacists and pharmacies shall not supply electronic equipment to any prescriber for transmitting prescription orders.

(6) An electronically transmitted prescription order shall be transmitted to the pharmacy of the patient's choice and shall be directed at the option of the patient.

(7) Prescription orders electronically transmitted to the pharmacy by the patient shall not be filled or dispensed.

(8) A prescription order may be transferred between pharmacies by computer but not by facsimile transmission. A prescription must be transmitted by facsimile from the site of origination to the dispensing pharmacy. Transmission by facsimile between pharmacies is not allowed except that a branch pharmacy may fax to its parent pharmacy.

R156-17a-618. Operating Standards - Sterile Pharmaceuticals.

In accordance with Subsection 58-17a-601(1), the following applies with respect to sterile pharmaceuticals:

(1) Pharmacies in general acute hospitals as defined in Title 26 that prepare sterile pharmaceuticals shall conform to the Joint Commission on Accreditation of Healthcare Organization standards, the American Society of Health-System Pharmacists guidelines, or other standards approved by the board and division.

(2) The following standards shall apply to all other pharmacies preparing sterile pharmaceuticals:

(a) Pharmacies are responsible for correct preparation of sterile products, notwithstanding the location of the patient. All sterile products must be prepared according to the current standards and ethics of the profession.

(b) As a minimum each pharmacy preparing parenteral products shall:

(i) prepare and maintain a policy and procedure manual for the compounding, dispensing and delivery of sterile pharmaceutical prescription drug orders including lot numbers of the components used in compounding sterile prescriptions except for large volume parenterals;

(ii) have a laminar flow hood certified at least annually by an independent contractor;

(iii) have appropriate disposal procedures and containers;

(iv) have biohazard cabinetry when cytotoxic drug products are prepared;

(v) have temperature-controlled delivery container;

(vi) have infusion devices, if appropriate;

(vii) have supplies and other necessary resources adequate to maintain an environment suitable for the aseptic preparation of sterile products;

(viii) have sufficient current reference materials related to sterile products to meet the needs of pharmacy staff; and

(ix) have written procedures requiring sampling for microbial contamination.

(c) The pharmacist-in-charge of each pharmacy preparing parenteral products shall assure that any compounded sterile pharmaceutical be shipped or delivered to a patient in appropriate temperature-controlled delivery containers with appropriate monitors and stored appropriately in the patient's home. If appropriate, the pharmacist must demonstrate or document the patient's or patient's agent's training and competency in managing this type of therapy provided by the pharmacist to the patient in the home environment. A pharmacist must be involved in the patient's or patient's agent's training

process in any area that relates to drug compounding, labeling, storage, stability, or incompatibility. The pharmacist must be responsible for seeing that the patient's or patient's agent's competency in the above areas is reassessed on an ongoing basis.

R156-17a-619. Operating Standards - Pharmaceutical Administration Facility.

In accordance with Subsection 58-17a-601(1), the following applies with respect to prescription drugs which are held, stored, or otherwise under the control of a pharmaceutical administration facility for administration to patients:

(1) The licensed pharmacist shall provide consultation on all aspects of pharmacy services in the facility; establish a system of records of receipt and disposition of all controlled substances in sufficient detail to enable an accurate reconciliation; and determine that drug records are in order and that an account of all controlled substances is maintained and periodically reconciled.

(2) Authorized destruction of all prescription drugs shall be witnessed by the medical or nursing director or a designated physician or registered nurse employed in the facility and the supervising pharmacist and must be in compliance with DEA regulations.

(3) Prescriptions for patients in the facility can be verbally requested by a licensed medical practitioner and may be entered as the physician's order; but, the practitioner must personally sign the order in the facility record within 72 hours, if a Schedule II controlled substance, and within 30 days if another prescription drug. The physician's verbal order may be copied and forwarded to a pharmacy for dispensing and may serve as the pharmacy's record of the prescription order.

(4) Prescriptions for controlled substances for patients in pharmaceutical administration facilities shall be dispensed according to the Utah Controlled Substance Act, Title 58, Chapter 37, and the Controlled Substance Rules of the Division of Occupational and Professional Licensing, R156-37.

(5) Emergency drug kit.

(a) An emergency drug kit may be used by pharmaceutical administration facilities. The emergency drug kit shall be considered to be a physical extension of the pharmacy supplying the emergency drug kit and shall at all times remain under the ownership of that pharmacy.

(b) The contents and quantity of drugs and supplies in the emergency drug kit shall be determined by the Medical Director or Director of Nursing of the pharmaceutical administration facility and the pharmacist-in-charge of the pharmacy.

(c) A copy of the approved list of contents shall be conspicuously posted on or near the kit.

(d) The emergency kit shall be used only for bona fide emergencies and only when medications cannot be obtained from a pharmacy in a timely manner.

(e) Records documenting the receipt and removal of drugs in the emergency kit shall be maintained by the facility and the pharmacy.

(f) The pharmacy shall be responsible for ensuring proper storage, security and accountability of the emergency kit and shall ensure that:

(i) the emergency kit is stored in a locked area and is locked itself; and

(ii) emergency kit drugs are accessible only to licensed physicians, physician assistants, and nurses employed by the facility.

(g) The contents of the emergency kit, the approved list of contents, and all related records shall be made freely available and open for inspection to appropriate representatives of the division and the Utah Department of Health.

R156-17a-620. Operating Standards - Pharmacist Administration - Training.

(1) In accordance with Subsection 58-17a-502(9), appropriate training for the administration of a prescription drug includes:

(a) having current BCLS certification; and

(b) having successfully completed a training program which includes at a minimum:

(i) didactic and practical training for administering injectable drugs;

(ii) the current Advisory Committee on Immunization Practices (ACIP) of the United States Center for Disease Control and Prevention guidelines for the administration of

immunizations; and

(iii) the management of an anaphylactic reaction.

(2) Sources for the appropriate training include:

(a) ACPE approved programs;

(b) curriculum-based programs from an ACPE accredited college of pharmacy; and

(c) state or local health department programs.

KEY: pharmacists, licensing, pharmacies

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